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EXAMINER

CHERESKIN, C

18M2/0623

ART UNIT

PAPER NUMBER

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DATE MAILED:

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on Apr. 5, 1993 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three(3) month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-4, 7, 15-19 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 5-6, 8-14 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-4, 7, 15-19 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Claims 1-4, 7, 15-19 remain. Claims 5-6, and 8-14 are cancelled.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

5 The rejection under 35 U.S.C. 112 second paragraph on page 2 of the previous office action is withdrawn in view of Applicants' amendments.

Claims 15-16 and 18-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Re claims 15 and 19, what is intended by "the sequence of and pattern of codons"? What is the difference between "sequence" and "pattern"? OK

Re claims 15 and 18, the language "about 130 to 140 kD delta-endotoxin gene" is confusing as to whether the gene or the protein encoded by the gene is 130-140 kD. OK

15 Re claims 15, and 18-19, "the amino-terminal portion of the gene" makes no sense as genes don't have an amino-terminal portion. OK

The rejection of claims 1-4, 7, and 15-18 under 35 U.S.C. 112, first and second paragraphs on page 2 of the previous office action is withdrawn in view of Applicants' amendments.

20 Claims 1-4, 7, and 15-19 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 Although it was previously suggested to limit the claims to "genes encoding B.t. delta-endotoxin proteins from about 130 to 140 kD", upon further consideration, the specification does not support such claim language.

The rejection under 35 U.S.C. 112 first paragraph on page 3 of the previous office action is withdrawn in view of Applicants' exhibits and arguments.

5 The rejection of claims 1-4, 7, and 15-18 under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to B.t. delta-endotoxin protein genes derived from genes encoding B.t. delta-endotoxin proteins from about 130 to 140 kD is withdrawn.

10 The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

15 The rejection of claims 1-4, 7, and 15-18 under 35 U.S.C. 103 as being unpatentable over Hoekema et al taken with Grantham et al, Schnepf et al, Vaeck et al, Barton et al, Hollenberg et al, and Seeburg et al is withdrawn. A new ground of rejection is set forth below. Applicants' arguments have been carefully considered with regard to this new ground of rejection.

20 Claims 15-19 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over any of Vaeck et al, Fischhoff et al or Barton et al.

25 Vaeck et al (Fig. 3, for example), Fischhoff et al (Fig. 5, 6, Table 1, for example) and Barton et al (Tables 1, 2, Fig. 2, for example) disclose transgenic dicot plants which express the amino-terminal portion of the delta-endotoxin gene of B. thuringiensis such that the plant was toxic upon ingestion to Manduca sexta

Vaeck et al, Fischhoff et al and Barton et al differ from the claimed invention in that the gene was not modified to utilize codons preferred in plants. However, the protein expressed in the transgenic plants was the same or an obvious variant of the protein expressed by Applicants. It would
5 have been expected by one of ordinary skill in the art that the truncated B.1. delta-endotoxin protein would be toxic to *Manduca sexta* upon ingestion, irregardless of the codons used to produce the protein. Applicants have not demonstrated that the expression and/or insecticidal capabilities of the claimed plants or DNA molecules (claim 19) were so high that they would
10 have been unexpected given the well known insecticidal properties of the truncated delta endotoxin proteins expressed in plants as taught by any of Vaeck et al, Fischhoff et al or Barton et al.

Consequently, the transgenic plants of Vaeck et al, Fischhoff et al or Barton et al appear to be very similar to the claimed transgenic plants and
15 DNA molecules of Applicant. However, even if the transgenic plants and DNA molecules of Vaeck et al, Fischhoff et al or Barton et al are not identical to the plants and DNA molecules claimed by Applicant, they appear to be so similar as to be a variant, well within the ordinary skill in the art to achieve.

Therefore, the claimed invention of Applicants, if not anticipated by,
20 would surely be rendered obvious by the disclosure of any of Vaeck et al, Fischhoff et al or Barton et al. Thus the claimed invention as a whole was at least clearly prima facie obvious if not anticipated by the references, in the absence of sufficient, clear, and convincing evidence to the contrary.

No claim is allowed.

25 An inquiry concerning this communication should be directed to Che Swyden Chereskin, Ph.D., at telephone number (703) 308-1180. Inquiries of a general nature should be directed to the Group 180 secretary at (703) 308-0196.

Serial No. 07/827,906
Art Unit 1804

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Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,
5 1989). The CM1 Fax Center number is (703) 308-4227.

CHE S. CHERESKIN
PRIMARY EXAMINER
GROUP 1800

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CSC

6-22-93

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